K012108

DEC 1 9 2001

POREX
SURGICAL PRODUCTS GROUP

510(k) SUMMARY

Manufacturer and Submitter

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

Contact: Howard Mercer, Ph.D.
e-mail: howard_mercer@porex.com

Date: November 5, 2001

Trade Name: MEDPOR® Coated Tear Drain
Class II Device
510(k) Number K012108

Substantially equivalent to:

A. MEDPOR® Surgical Implant Material

B. Pre-amendment borosilicate glass Jones tube

Device description:

The device of this submission is identical to the predicate devices except that the MEDPOR® Porous Polyethylene is formed around the glass tube.

Indications for Use:

An implant to bypass the obstructed lacrimal drainage system for the treatment of chronic epiphora.

Porex Surgical, Inc.
15 Dart Road • Newnan, GA 30265-1017 USA • TEL 1-800-521-7321 • 1-678-479-1610 • FAX 1-678-423-1435

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

Attn: Howard Mercer, Ph.D.
Regulatory Affairs Manager
Porex Surgical, Inc.
150 Dart Road
Newman, GA 30265

Re: K012108
Trade/Device Name: Medpor coated tear drain
Regulatory Class: Unclassified
Product Code: OKS (Lacrimal System Repair Device)
Dated: November 5, 2001
Received: November 7, 2001

Dear Dr. Mercer:

This letter corrects our substantially equivalent letter of December 19, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

Applicant: Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

510(k) Number: K012108

Device Name: MEDPOR® Coated Tear Drain

Indications for Use:

An implant to bypass the obstructed lacrimal drainage system for the treatment of chronic epiphora.

(PLEASE DO NOT WRITE BELOW THIS LINE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K012108

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21CFR801.109